Emergency Adoption 36 NJR 6(1)
June 7, 2004

**HEALTH AND SENIOR SERVICES**

**DIVISION OF PUBLIC HEALTH AND ENVIRONMENTAL LABORATORIES**

**Limited Purpose Laboratories**

**Adopted Emergency and Concurrent Proposed New Rules: N.J.A.C. 8:44-3**

**Emergency New Rules Adopted and Concurrent Proposed New Rules**

**Authorized: _____, 2004, _____ by Clifton R. Lacy, M.D., Commissioner, Department of Health and Senior Services (with the approval of the Public Health Council)**

**Emergency Rule Filed: May 18, 2004 as R. 2004 d.219**

**Gubernatorial Approval (N.J.S.A. 52:14B-4(c)): May 18, 2004**

**Authority: N.J.S.A. 26:1A-7 and 45: 9-42.34**

**Calendar Reference: See Summary below for explanation of exception to calendar requirement.**

**Concurrent Proposal Number: PRN 2004-241**

**Emergency Adoption Effective Date: May 19, 2004**

**Emergency Adoption Expiration Date: July 18, 2004**

**A public hearing concerning this proposed new rule will be held on Monday, July 12, 2004 at 10:00 A.M. in the First Floor Auditorium, Health and Agriculture Building, John Fitch Plaza, Trenton, New Jersey 08625**

**Submit written comments to be received by July 7, 2004 to:**

**Dennis P. McDonough, M.P.H., Director
Clinical Laboratory Improvement Service
Department of Health and Senior Services
Health and Agriculture Building, Room 405
P.O. Box 361
Trenton, N.J. 08625-0361
Fax: (609) 633-9601
E-Mail: dennis.mcdonough@doh.state.nj.us**

This is an emergency adoption and concurrent proposal by the Department of Health and Senior Services, with the approval of the Public Health Council, to permit rapid point of care testing for the Human Imunodeficiency Virus (HIV) by Department funded HIV counseling and testing facilities under a limited purpose laboratory license. These rules are proposed for adoption on an emergency basis and will become effective upon acceptance for filing by the Office of Administrative Law (see N.J.S.A. 52:14B-4(c) as implemented by N.J.A.C. 1:30-6.5(b)). Concurrently, the provisions of this emergency adoption are proposed for readoption pursuant to the normal rulemaking requirements of the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq. The rules become effective upon acceptance for filing by the office of Administrative Law (N.J.A.C. 1:30-6.5(d)), if filed on or prior to the emergency expiration.

The agency emergency adoption and concurrent proposal follows:

## Summary

On November 7, 2002, the U.S. Food and Drug Administration approved a rapid diagnostic test for Human Immunodeficiency Virus (HIV), the virus that causes AIDS. This test cannot be currently performed in New Jersey without a Department issued clinical laboratory license and compliance with licensure standards including, but not limited to, a qualified director, quality control and quality assurance, proficiency testing, personnel and recordkeeping.

The rapid HIV test is considered a point of care (POC) procedure that can be performed while a patient receives HIV counseling. The patient can be informed of the HIV test results and, if HIV-positive, immediately counseled about available treatment services and educated about how to prevent transmission of the virus to others. The Department's 24 funded counseling and testing sites with 158 satellite locations offer many advantages as providers of the rapid HIV point of care test. More than 65,000 people were tested for HIV in 2002 at the counseling and testing sites. However, these sites cannot meet current clinical laboratory standards, especially for personnel and the rapid HIV test requires that care be taken to ensure that testing adheres to standards of laboratory practice in order to produce valid test results.

Emergency adoption is necessary in order to make technological advances in laboratory testing methods available to these counseling and testing facilities funded by the Department of Health and Senior Services, Division of HIV/AIDS Services. Current testing methods require patients to return to the counseling and testing facility seven to 10 days after testing to receive their test results. In calendar year 2002, 23,070 persons or 35 percent of those tested for HIV did not return for their test results. Of these, there were 381 HIV-positive persons who did not return for their test results and consequently did not access available HIV treatment services and continued to be a source of HIV infection to others in their communities. The 381 HIV-positive persons not returning for test results have an average of four sexual and/or needle sharing partners, thereby exposing more than 1,500 additional people to HIV disease. Those who are or become pregnant are at risk of transmitting HIV to their unborn child.

A six-month pilot project which implemented HIV rapid testing at five counseling and testing sites with licensed clinical laboratories tested a total of 1,013 patients, all of whom received their test results and post test counseling. Forty-two persons or four percent were identified as HIV-positive, which is twice the percentage (that is, two percent) of HIV-positive persons identified using the non-rapid test in 2002. In addition, 27 of the 42 or 64 percent were previously undiagnosed patients, compared to 50 percent of positive results using non-rapid testing methods. Implementation of the rapid HIV point of care test under emergency rulemaking will enable New Jersey's Department funded counseling and testing sites to identify an estimated 150 to 200 HIV-positive persons during testing visits over the next six months, the period of time that it would take for the concurrent new rule proposal to go through the formal administrative rule adoption process before becoming effective, who would not otherwise have returned to receive their test results. These HIV-positive persons will be advised of the testing results and counseling and testing facilities will initiate immediate confirmatory testing, and treatment and prevention interventions according to established protocols, thereby reducing the risk of HIV exposure from these HIV-positive persons to between 600 and 800 sexual and needle sharing partners over the next six months. As such, it is in the public's best interests to allow for the immediate use of this new testing procedure under limited and controlled conditions.

This emergency rulemaking and concurrent proposed new rule are warranted in order to protect the public health of New Jersey's residents by identifying an estimated 150 to 200 HIV-positive persons over the next six months who would not otherwise return to receive their HIV test results, reducing HIV viral loads in these persons through access to treatment and medications, and reducing the number of unidentified and untreated HIV-

positive persons who would otherwise continue to serve as a source of HIV infection to others in their communities.

Balancing the need to increase the number of individuals receiving their HIV test result coincident with their receiving counseling services and the need to ensure that this new point of care test is performed in a manner that provides accurate test results, the Department is proposing a new designation for laboratories in New Jersey to be known as a “limited purpose laboratory.” Facilities eligible to become a limited purpose laboratory (LPL) will be limited to Department-funded not-for-profit, free standing **c**ounseling and testing sites (CTS) whose mission is to provide HIV counseling and testing services. Testing performed at these sites will be limited to an FDA approved rapid POC test for Human Immunodeficiency Virus (HIV). LPL designation has been limited to CTS because of the added control the Department has over these facilities since they are required to follow grant specifications established by the Division of HIV/AIDS Services. These requirements include adherence to Department established procedures and protocols, and participation in Department sponsored training for counseling and testing. Limited Purpose Laboratories will not need to meet all the licensure requirements necessary to become a clinical laboratory. Of particular significance is the waiving of the requirements for the qualifications and education of the general supervisor, technical supervisor and technical personnel in N.J.A.C. 8:44-2.4 and 2.6.

Subchapter 3, Limited Purpose Laboratory, proposes to create and regulate the limited purpose laboratory in order to permit testing in free standing counseling and testing sites (CTS) operated by a non-profit organization receiving grant funds from the Department, and limit testing to FDA approved rapid point-of-care testing for HIV. It will

provide for the appropriate level of regulatory oversight and on-site inspection of sample handling/testing procedures and protocols, director qualifications, personnel supervision, quality control, proficiency testing and management of test requests, records and results, and establishes licensure fees.

A summary of the agency emergency adopted and concurrent proposed new rules follows:

N.J.A.C. 8:44-3.1 defines what type of facility may be licensed as a Limited purpose laboratory and identifies the minimum operational protocols that the laboratory must establish.

N.J.A.C. 8:44-3.2 restricts applicability of these rules to facilities meeting the definition of limited purpose laboratory and requires that each site be licensed.

N.J.A.C. 8:44-3.3 establishes the qualifications of the laboratory director, the number of limited purpose laboratories that a laboratory director may oversee and identifies responsibilities of the laboratory director.

N.J.A.C. 8:44-3.4 identifies the requirements for supervision of the limited purpose laboratory by a general supervisor, requires review of specified facility records on at least a monthly basis, requires that testing personnel be trained in accordance with the Centers for Disease Control and Prevention (CDC) Quality Assurance Guidelines for Testing using the OraQuick HIV-1 Antibody Test (CDC Quality Assurance Guidelines), which are incorporated herein by reference, as amended and supplemented and available at http://www.cdc.gov/hiv/rapid_testing/materials/QA-Guide.htm which address the availability of step-by-step testing instructions for testing personnel, review of manufacturer's

instructions, use of protective equipment, waste disposal, quality control testing, collection and testing of specimens, recordkeeping, and other provisions established to produce valid test results, and authorizes the Department to approve new rapid HIV point of care tests for use by the limited purpose laboratory.

N.J.A.C. 8:44-3.5 provides that only tests approved by the Department may be performed by the limited purpose laboratory, specifies requirements for proficiency testing and allows the non-profit organization to promote or advertise the availability of testing.

N.J.A.C. 8:44-3.6 requires that records be maintained by the limited purpose laboratory including documentation of staff training addressing all areas included in the CDC Quality Assurance Guidelines as well as protocols for the management of occupational exposures to bloodborne pathogens in order to minimize the risk of exposure to testing personnel to HIV and other bloodborne diseases in accordance with Appendix A Practice Recommendations for Healthcare Facilities Implementing the U.S. Public Health Service Guidelines for Management of Occupational Exposures to Bloodborne Pathogens as issued by the CDC and available at http://www.cdc.gov/mmwr/indrr_2001.html, incorporated by reference, as amended and supplemented.

N.J.A.C. 8:44-3.7 provides that a procedure manual be maintained for all protocols and procedures used for testing and requires approval by the laboratory director at least annually.

N.J.A.C. 8:44-3.8 provides that space and facilities shall be adequate for the services offered by the limited purpose laboratory.

N.J.A.C. 8:44-3.9 establishes that trained personnel may collect blood for testing under the direction of the laboratory director

N.J.A.C. 8:44-3.10 provides for the proper disposal of waste materials in accordance with state statutes and regulations.

N.J.A.C. 8:44-3.11 establishes recordkeeping requirements for the identification of patient specimens for testing including personal identifiers, date and time of testing and results.

N.J.A.C. 8:44-3.12 directs that patient testing is performed under a physician's order or other person authorized by law, that test results be reported to the patient by a Department trained HIV counselor, and that a patient may request test results to be sent to a designated physician.

N.J.A.C. 8:44-3.13 directs that copies of the test reports shall be maintained for at least two years, shall be accessible and enable identification of patients tested.

N.J.A.C. 8:44-3.14 sets forth the requirements for quality control and quality assurance activities at least equal to CDC guidelines to ensure proper performance of testing, including adequacy of facilities and methods, adherance to proper temperatures for test kit storage and testing, specimen adequacy and recordkeeping.

N.J.A.C. 8:44-3.15 prescribes the licensure fee for a limited purpose laboratory, late fees and a fee for a change of address requiring license replacement.

N.J.A.C. 8:44-3.16 establishes that a limited purpose laboratory comply with licensing and proficiency testing provisions in regulation and specifies that any authorized representative of the Department may conduct an inspection of the facility to determine compliance.

Pursuant to its authority under N.J.S.A. 52:14B-4(c), the Department of Health and Senior Services intends the concurrent proposal to be permanently codified at N.J.A.C. 8:44-3 upon the filing of its notice of adoption with the Office of Administrative Law.

As involving an imminent peril subject to provisions of N.J.S.A. 52:14B-4(c), this rulemaking is excepted from the rulemaking calendar requirement by N.J.A.C. 1:30-3.3(a)3.

## Social Impact

The Division of Public Health and Environmental Laboratories, through its Clinical Laboratory Improvement Service (CLIS), monitors the quality of patient laboratory testing via licensure, inspection and proficiency testing to assure compliance with stated standards and to maintain acceptable levels of performance for New Jersey residents. The proposed new rules are consistent with this mission and the ongoing effort by the Department's Division of HIV/AIDS Services to ensure that New Jersey citizens have access to information regarding their HIV status. Currently, HIV diagnostic laboratory testing must be performed in New Jersey by a licensed clinical laboratory and requires that a patient return a week to 10 days later to obtain their test result and learn their HIV status. The proposed new rules will permit the rapid diagnostic HIV test to be performed in Department funded HIV counseling and testing sites which are licensed as limited purpose laboratories, and for patients to receive test results the same day.

Presently in New Jersey, many people do not return to receive their results. The average percentage of people who returned for their results and post test counseling at the publicly funded counseling and testing sites in New Jersey for 2002 was 65 percent

(43,693 of 66,763 tests performed). Therefore, 23,070 people were tested but did not return to receive their test results. Availability of rapid testing is expected to significantly increase the number of people tested who learn their HIV status, access medical care, and reduce the risk of HIV transmission to others.

## Economic Impact

There will be no direct economic impact on the taxpayers of New Jersey because the necessary annual licensure fees and operating costs for a "limited purpose laboratory" to provide publicly funded HIV counseling and testing will be financed through Federal funding. There will be an indirect economic benefit to the public as a whole since those requesting HIV testing in this setting will be provided with testing services in a CTS with the necessary and appropriate level of regulatory oversight, thus reducing the potential for inaccurate testing results and the unnecessary medical costs associated with this occurrence. Those identified as infected with HIV through this screening test protocol will also require confirmatory testing be performed and will be referred for care and treatment. It is estimated that this conversion will increase the detection of 400 additional HIV infected persons each year, prevent HIV transmission to 14 people each year, and provide a savings of $26.59 for each test compared to current protocols. Treatment of HIV disease has been shown to improve length-of-life and quality-of-life and allows HIV infected persons to remain in or return to the work force. The economic savings from avoiding transmission to 14 people in just the first year of rapid testing is $2,475,002 in treatment

costs over their lifetime. All current components of counseling and testing will remain intact.

## Federal Standards Analysis

The proposed new rules for limited purpose laboratories (LPLs) performing Food and Drug Administration (FDA) approved rapid HIV point of care (HIV POC) testing is more stringent than Federal regulations promulgated pursuant to the Clinical Laboratory Improvement Amendments of 1988 (CLIA' 88) in three areas. The more stringent standards are described and justified below.

N.J.A.C. 8:44-3.3 provides that a limited purpose laboratory shall be under the direction of a laboratory director as specified in N.J.A.C. 8:44 2.3(b) 2, 3, 4 and 5 and 2.3(c). These regulations require that a physician or other qualified individual with a doctoral degree, who holds a bioanalytical laboratory director license, shall serve as laboratory director. Federal FDA and CLIA '88 regulations require that purchasers/users of the HIV POC test be a clinical laboratory holding a valid CLIA '88 certificate of waiver, compliance or accreditation. A CLIA '88 certificate of waiver, which is what the proposed HIV POC limited purpose laboratories performing this testing will obtain, does not require the laboratory director to meet the proposed requirements referenced in N.J.A.C. 8:44-3.3(a). It must be recognized, however, that the individuals conducting the HIV POC testing in Department-funded HIV counseling and testing programs are not health care professionals such as physicians, nurses and medical technologists. In New Jersey, most

CLIA ’88 certificates of waiver are issued to physician offices, nursing homes and/or schools where waived testing is performed by a nurse or other individual under the supervision of the physician. The proposed limited purpose laboratory regulations will permit a qualified laboratory director to oversee multiple LPLs. The requirement for a qualified laboratory director is intended to ensure that the HIV POC testing to be performed by non-laboratory personnel in Department-funded counseling and testing facilities is conducted in accordance with the manufacturer’s instructions, including the training of testing personnel and the establishment of, and adherence to, a quality assurance program. The laboratory director of the limited purpose laboratories will be responsible for ensuring that testing is being carried out correctly, that test results are accurate, and that mistakes are found and corrected to avoid adverse outcomes, both to clients being tested and to counseling and testing staff conducting the testing.

The proposed N.J.A.C. 8:44 3.5(b) will require participation of limited purpose laboratories in a Department approved proficiency testing program. Federal CLIA ‘88 regulations do not require proficiency testing for waived tests. However, unlike many other waived tests, the consequences of inaccurate HIV testing results can result in extreme duress to a negative client who is incorrectly identified as positive due to poor laboratory practices, and conversely, the failure to properly identify clients who are positive may result in continued risk of HIV transmission to uninfected individuals engaging in at risk behaviors with infected persons. Proficiency testing is an integral component of a quality assurance program. Participation in an approved proficiency testing program will provide the Department and the public an important objective indicator that testing being conducted by personnel in Department-funded counseling and testing programs is producing valid test

results. The cost of proficiency testing will be supported by grant funds from the Department to the counseling and testing programs.

The proposed regulations for Quality Control and Quality Assurance at N.J.A.C. 8:44-3.14 are intended to ensure that all aspects of the HIV point of care testing to be conducted at Department-funded HIV counseling and testing programs serve to produce valid test results. While Federal regulations do not prescribe these requirements for laboratories performing the HIV-POC testing, the FDA in its approval of the instructions for test kit users, specifies that sale of the HIV POC test kit is restricted to clinical laboratories "that have an adequate quality assurance program, including planned systematic activities to provide adequate confidence that requirements for quality will be met; and where there is assurance that operators will receive and use the instructional materials." The Department believes that the quality control provisions contained in N.J.A.C. 8:44-3.14 are consistent with the intent of the FDA approved instructions and CLIA '88 regulations, which require adherence to manufacturer's instructions for performing the HIV POC test.

All costs of the additional requirements imposed by the proposed new rules will be supported by grant funds from the Department, thereby enabling all limited purpose laboratories licensed under this proposal to comply with the new rules.

## Jobs Impact

It is the position of the Department that the proposed new rules will have no impact on jobs to be generated or lost as a result of their promulgation.

## Agriculture Industry Impact

The proposed new rules will have no impact on the agriculture industry.

## Regulatory Flexibility Analysis

The proposed subchapter is applicable to all not-for-profit and State or local government facilities operated by an agency funded through the Department, and limited to FDA approved rapid point of care testing for Human Immunodeficiency Virus (HIV). The non-for profit facilities might be considered small businesses under the Regulatory Flexibility Act, N.J.S.A. 52:1B-16 et seq.

The proposed subchapter will affect twenty-four existing HIV counseling and testing Sites currently receiving grant funds from the Department and the existing satellite facilities they operate to maximize public accessibility to HIV counseling and testing services. Compliance requirements are discussed in the summary above. Existing staff have been trained and additional training will be provided to ensure that the rapid HIV test is performed correctly. No new staff are required to comply with the provisions of the Limited purpose laboratory rules and no other facilities are affected by the rules other than those currently receiving grant funds from the Department. Licensure fees and operating costs will be met through Federal funding

## Smart Growth Impact

The proposed new rules will have no impact on the achievement of smart growth or the implementation of the State Development and Redevelopment Plan.

**Full text** of the emergency adopted and concurrent proposed new rules follows:

## SUBCHAPTER 3. LIMITED PURPOSE LABORATORY

### 8:44-3.1 Limited purpose laboratory; definition and minimum protocols

**(a) "Limited purpose laboratory" means a facility operated by a not-for-profit organization receiving grant funds from the Department of Health and Senior Services, hereinafter known as the Department, to operate a counseling and testing site to conduct rapid FDA licensed point-of-care tests for Human Immunodeficiency Virus (HIV).**

**(b) A limited purpose laboratory shall establish the following protocols at a minimum:**

**1. Follow-up protocols to ensure that Food and Drug Administration (FDA) approved confirmatory testing is performed**;

2. **A protocol for the review of test results by the laboratory director and general supervisor**;
3. **Protocols to ensure that individuals with abnormal results are referred to an appropriate source of medical care and prevention services; and**
4. **Personnel policies, practices and procedures that adequately support sound rapid FDA licensed point-of-care testing practices.**

**8:44-3.2 Applicability of subchapter**

**(a) The subchapter applies to limited purpose laboratories as defined in N.J.A.C. 8:44-3.1(a).**

**(b) If a limited purpose laboratory is operated at more than one site, each site shall require a separate license.**

**8:44-3.3 Director**

**(a) A limited purpose laboratory shall be under the direction of a laboratory director as specified in N.J.A.C. 8:44-2.3(b) 2, 3, 4, and 5, and 2.3(c).**

**(b) The laboratory director can direct multiple limited purpose laboratories which share a quality assurance program and laboratory policies and these shall count as one clinical laboratory for the purpose of N.J.A.C. 8:44-2.3(b)1. The laboratory director can direct no more than five limited purpose laboratories whose quality assurance program and**

**laboratory policies are not identical and these shall count as one clinical laboratory for the purpose of N.J.A.C. 8:44-2.3(b)1.**

**(c) The laboratory director shall, at a minimum, serve the limited purpose laboratory on a regular part-time basis to ensure that the provisions of this subchapter are met.**

**(d) The laboratory director shall be readily available for personal or telephone consultation with staff.**

**(e) The laboratory director shall be responsible for the proper performance of all testing procedures and for ensuring the competency of all persons performing point of care testing.**

**(f) The laboratory director shall arrange for a qualified substitute director, prior to the director's absence.**

**8:44-3.4 Supervision**

**(a) A limited purpose laboratory shall be supervised by a person, designated as the general supervisor, who can be, but is not limited to being, a physician, professional registered nurse, counseling and testing site coordinator, or health educator, approved by the laboratory director, who, under the general direction of the laboratory director,**

**supervises testing personnel and the report of findings, and in the absence of the laboratory director, is responsible for the proper performance of all laboratory procedures.**

**1. Limited purpose laboratory records including, but not limited to, patient accession, testing, test results, quality control and temperature monitoring, shall be reviewed at least monthly by the laboratory director, general supervisor, or qualified designee of the laboratory director.**

**(b) The rapid FDA licensed point-of-care test for Human Immunodeficiency Virus (HIV) shall be performed by personnel, such as professional registered nurses, technicians or non-professionals, who have been trained in accordance with the provisions of the Centers for Disease Control and Prevention (CDC) Quality Assurance Guidelines for Testing using the OraQuick Rapid HIV-1 Antibody Test, hereinafter known as the CDC Quality Assurance Guidelines which are incorporated herein by reference, as amended and supplemented, and available at http://www.cdc.gov/hiv/rapid_testing/materials/QA-Guide.htm. The laboratory director shall develop testing and operational protocols, which meet or exceed those issued by the CDC.**

**(c) The laboratory director shall revise quality assurance, testing, and operational protocols and provide training of testing personnel and supervisors, for any new additional point of care rapid HIV test authorized by the Department for use in limited purpose laboratories subsequent to the adoption of these regulations.**

**8:44-3.5 Screening tests performed**

**(a) A limited purpose laboratory shall perform only those tests and procedures that are expressly approved by the Department pursuant to N.J.A.C. 8:44-3.1(a).**

**(b) A limited purpose laboratory shall perform proficiency testing in accordance with N.J.A.C. 8:44-2.5(b) for each location where testing is performed except where multiple limited purpose laboratories are operated by the same non-profit organization and share the same laboratory director, quality assurance program, policies and procedures and testing personnel, proficiency testing can be performed at one limited purpose laboratory location.**

**(c) A limited purpose laboratory or sponsoring organization may promote the testing services offered by the limited purpose laboratory by advertising, community outreach program and any other means of public notice.**

**8:44-3.6 Management of a limited purpose laboratory**

**A limited purpose laboratory shall maintain records and facilities that are adequate and appropriate for the services offered. There shall be documentation of appropriate training for staff involved in the implementation of these procedures and methods. The training shall address all areas included in the CDC Quality Assurance Guidelines and shall include protocols for the management of occupational exposures to bloodborne pathogens following Appendix A Practice Recommendations for Health Care Facilities Implementing the U.S. Public Health Service Guidelines for Management of Occupational Exposures to Bloodborne Pathogens, published in Volume 50/No. RR-11 of the Morbidity and Mortality Weekly Report issued by the CDC and available at http://www.cdc.gov/mmwr/indrr_2001.html, incorporated herein by reference, as amended and supplemented.**

**8:44-3.7 Procedure manual**

**A procedure manual shall be kept for all protocols and all procedures used for the rapid FDA licensed point-of-care test for Human Immunodeficiency Virus (HIV) performed or offered by the limited purpose laboratory. Each protocol or procedure shall be reviewed and dated by the laboratory director at least annually.**

**8:44-3.8 Facilities**

**Space and facilities shall be adequate to properly perform the services which are offered by the limited purpose laboratory.**

**8:44-3.9 Collection of specimens**

**Properly trained personnel designated by the laboratory director of the limited purpose laboratory may collect blood or material for screening and/or confirmatory procedures from an individual patient, under the direction of the laboratory director.**

**8:44-3.10 Disposable equipment**

**(a) Syringes, needles, lancets, or other bloodletting devices capable of transmitting infection from one person to another shall not be reused and shall be in conformance with N.J.S.A. 26:2H-5.12 et seq., New Jersey Safety Needle Act, and with Federal regulations at 29 C.F.R. 1910.1030.**

**(b) Management and disposal of all regulated medical waste shall be in conformance with the New Jersey Regulated Medical Waste Management Act, N.J.S.A.13:1E-48.1 et seq., and N.J.A.C.7:26, Regulated Medical Waste.**

**8:44-3.11 Records of specimens**

**(a) A limited purpose laboratory shall maintain a record indicating the daily accession of specimens, each of which is numbered or otherwise appropriately identified. Records shall contain the following information:**

1. **The number or other identification of the specimen;**
2. **The name or other identification that can be linked to a person or anonymous client from whom the specimen was taken;**
3. **The date the specimen was collected and tested;**
4. **The time the test is started and when the test is read, for time dependent tests;**
5. **The results of the test including all duplicate or invalid test results;**
6. **The Identity of the person performing the test;**
7. **The name and address of the laboratory where confirmatory testing is performed; and**
8. **Date confirmatory test specimen sent and date test results received by the referring limited purpose laboratory.**

**8:44-3.12 Examinations and reports**

(a) A limited purpose laboratory shall perform tests at the request of a licensed physician or other person qualified by law to order tests. The request need not be patient specific and can be a standing order.

(b) The results of the rapid FDA licensed point-of-care test for Human Immunodeficiency Virus (HIV) performed by a limited purpose laboratory shall be conveyed to the patient by a New Jersey Department of Health and Senior Services trained HIV counselor.

(c) When requested, the original or true duplicate of the results shall be sent promptly to the physician who is designated by the individual patient to receive a report.

**8:44-3.13 Report records**

True duplicate copies or a suitable record of test reports shall be filed in the limited purpose laboratory in a manner which permits ready identification and accessibility. All reports shall be preserved for a period of at least two years after the date of the test.

**8:44-3.14 Quality control and quality assurance**

(a) Quality controls imposed on and practiced by the limited purpose laboratory shall provide for and include written records to assure the following:

1. **Preventive maintenance, periodic inspection, and testing for proper operation of equipment as may be appropriate based on the frequency of the testing sessions and on the number of tests performed; evaluation of reagents; surveillance of results; and remedial action to be taken in response to detected defects;**
2. **Adequacy of facilities, equipment, and methods for performance of the procedures for which licensure is approved; proper lighting for accuracy and precision; convenient location of essential utilities; monitoring of temperature-controlled spaces and equipment to assure proper performance; and evaluation of analytical measuring devices with respect to all critical operating characteristics;**
3. **Labeling of all reagents and solutions to indicate identity, recommended storage requirements, expiration date, and other pertinent information. Materials of substandard reactivity and deteriorated materials shall not be used. All outdated material shall be discarded immediately;**
4. **The availability at all times, in the immediate bench area of personnel engaged in examining specimens and performing related procedures, of current laboratory manuals or other complete written descriptions and instructions relating to:**

i. **The methods used by those personnel, properly designated and dated to reflect the most recent supervisory reviews;**

ii. **Reagents; and**

iii. **Control procedures;**

5. **Written approval by the laboratory director of all changes in laboratory procedures;**

6. **Maintenance and availability of records to laboratory personnel and to the Department, reflecting dates and, where appropriate, the nature of inspection, validation, remedial action, monitoring, evaluation and changes and dates of changes in laboratory procedures; and**

7. **Acceptance by the limited purpose laboratory of only specimens that have been properly collected, labeled, processed, in such a manner as to assure identity of the specimen with respect to the requested tests.**

**(b) Provision shall be made for an acceptable quality assurance program that follows the CDC Quality Assurance Guidelines for rapid FDA licensed point-of-care tests for HIV or, if developed by the laboratory director, is equal to or more stringent than the CDC Quality Assurance Guidelines which are available at http://www.cdc.gov/hiv/rapid_testing/materials/QA-Guide.htm. The quality**

**assurance program shall verify and evaluate the accuracy and precision of the testing process and be able to detect errors in the testing process.**

**8:44-3.15 Initial and renewal licensure fees**

**(a) Licensure fees for the limited purpose laboratory are not specified in N.J.A.C. 8:45-1.3.**

**(b) Initial and annual renewal licensure fees for the limited purpose laboratory shall be prescribed as $100.00 per location.**

**(c) Limited purpose laboratories shall remit an additional fee of $50.00 for renewal applications when the renewal application does not meet the November 1 deadline specified in N.J.A.C. 8:45-1.2(b) and it is submitted after December 31.**

**(d) Limited purpose laboratories shall pay a fee of $50.00 for replacement of a license due to change of address.**

**8:44-3.16 Compliance**

**(a) The limited purpose laboratory shall comply with the provisions set forth in this subchapter and the following:**

**1. Licensure requirements as specified in N.J.A.C. 8:45-1.1 and 1.2; and**

**2. Inspections of the limited purpose laboratory by any authorized representative of the Department of Health and Senior Services.**